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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,054	03/10/2000	Shyam S. Mohapatra	0152.00355	4567

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EXAMINER

SCHEINER, LAURIE A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 11/18/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/523,054

Applicant(s)
Behera et al.

Examiner
Laurie Scheiner

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 5, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 7-9 and 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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Claims 1-18 are pending in this application. Claims 7-9 and 13-18 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-6 and 10-12 are considered below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The specification fails to support the administration of agent orally or by inhalation since the mode of administration is agent dependent. That is, the agent is unknown. The agent is unknown and therefore cannot be administered by a particular route since the specification fails in written support. An unknown agent employed in a general method claim cannot be limited by a more narrowly defined route of administration since the correlated limitations are lacking from the specification. A pharmaceutically acceptable carrier is contemplated. However, the carrier is both agent and administration route dependent. It is asserted that the agent is unknown and the route of administration is unsupported. Again, oral and inhalation routes of administration are not supported by the specification and would be necessarily agent dependent. The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone

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skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell*, 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). *In re Deuel*, 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995). Demonstration of possession of invention is problematic when broad conceptual methods recite narrow process limitations not supported by an adequate written description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3 and 10-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Patel. et al. (American Journal of Respiratory Cell and Molecular Biology, (1995) Vol. 13, No. 5, pp. 602-609) for reasons of record.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumasaka et al. (J. Clin. Invest. 97:2362-2369, 1996) for reasons of record.

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Applicant's arguments filed September 5, 2002 have been fully considered but they are not persuasive.

With respect to the rejection of claims over Patel et al under 35 U.S.C. 102(b) applicants argue that anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

Applicants' are reminded that the instant claims are drawn to methods rather than structures. Moreover, the instant methods are anticipated by the reference.

Applicants argue that the present invention differs from Patel et al. by establishing that by blocking ICAM-1, the viral replication and spread in the epithelial cells of the lungs is limited. Applicants further argue that the blockers would work similar to that of a vaccine, however, vaccines were neither shown nor suggested by Patel et al.

The examiner contends that no ICAM-1 blocking limitation is recited by the rejected claims. Moreover, the claims are neither drawn to blockers nor vaccines. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants interpret Patel et al's findings and conclude that since ICAM-1 is a proinflammatory molecule, by blocking ICAM-1, the RSV inflammation is decreased.

The examiner contends that by their statement, applicants appear to contradict their above position with respect to blocking ICAM-1. Contradiction aside, Patel et al's methods necessarily function in accordance with the instant limitations of the claims since their method steps are identical to instant method steps irrespective of any interpretations of mechanism. Applicants are reminded that although their arguments are drawn to preventing RSV infection, claims 1-6 make no mention of said RSV.

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Applicants also argue that the antiviral mechanism of the ICAM-1 antibody or soluble ICAM-1 has not been previously demonstrated.

The examiner contends that applicants' claims are not limited to ICAM-1 antibody or soluble ICAM-1. Moreover, mechanisms in the absence of discrete process limitations are not patentable.

With respect to the rejection of claims 1 and 2 over Kumasaka et al. under 35 U.S.C. 102 (b), applicants argue that the reference does not pertain to RSV infection, nor does it pertain to viral respiratory infection.

The examiner contends that the claims are not limited to RSV infection. Moreover, with respect to viral respiratory infection, applicants are reminded that the preamble of the claim is not given patentable weight and it is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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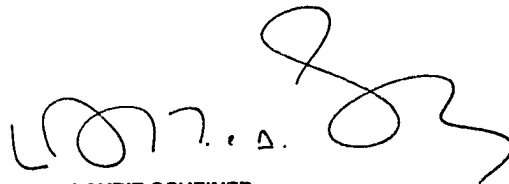
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.



Laurie Scheiner/LAS
November 14, 2002



LAURIE SCHEINER
PRIMARY EXAMINER